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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/890,649 | 10/26/2001 | Michael W. Dahn | 24741-1529 | 5173 |

7590 08/25/2005

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| EXAMINER |
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CANELLA, KAREN A

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| ART UNIT | PAPER NUMBER |
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1643

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,649

Applicant(s)

DAHME ET AL.

Examiner

Karen A. Canella

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 9 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 36-48 and 51-87 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 36-38, 51-55, 77-79 and 81-87 is/are rejected.
- 7) ☐ Claim(s) 39-48, 56-76 and 80 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Claims 36-48 and 51-87 are pending and under consideration.
2. Sections of title 35, U.S. Code not found in this action can be found in a prior action.
3. The rejection of claim 87 under 102(e) as being anticipated by Ts'o et al (US 5,962, 237) is maintained for reasons of record. This is a product by process claim. Ts'o disclose the culture of tumor cell lines obtained by the disclosed methods. The tumor cells isolated by the method of Ts'o would have the same characteristics as the corresponding tumor cells isolated by the instant methods.
4. Applicant has not provided any argument why the tumor cell culture of claim 87 would be patentably distinct from the tumor cell culture of Ts'o et al. Applicant argues that the tumor cell culture of Ts'o does satisfy every element of claim 36 in that the instant method makes it possible to enrich for disseminated tumor cells of different types while significantly reducing unwanted blood cells which might interfere with further purification steps. This has been considered but not found persuasive. The use of the multiple gradient as disclosed by Ts'o et al would effectively enrich for disseminated tumor cells and eliminate unwanted tumor cells, and the production of a tumor cell line from cells isolated by the method of Ts'o et al would result in the same tumor cell lines as the instant claim 87. As stated in the previous Office action, claim 87 is a product-by process-claim and it is clearly sated in the M.P.E.P (2113) that
PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS
Therefore, a tumor cell line of the instant invention would be anticipated by a tumor cell line of Ts'o et al because the tumor cell lines would be the same, irregardless of the differences between the production of each cell line.
5. The rejection of claims 36-38 and 51-55 under the judicially-created doctrine of obviousness-type double patenting over claims 27, 28, 29, 30, 31, 48 and 49 of US 6, 821, 726 is

Art Unit: 1643

maintained until such time that a terminal-disclaimed which fully complies with 37 CFR 3.73(b) is filed.

6. The rejection of claims 77-79 and 81-86 under 35 U.S.C. 102(b) as being anticipated by Ayres (US 3, 945, 928) is maintained for reasons of record.

Ayres disclose a tubular container closed at both ends; elastomeric barrier means fixedly located intermediate the container ends attached to the inner side wall of the container and dividing the container into first and second chambers such that upon separation of the blood into the light phase and the heavy phase by the application of centrifugal force, the first chamber contains only the light phase; a passageway through the barrier means connecting the first and second chambers, said barrier means further including a conical surface, adjacent the first chamber, which forms a funnel that is in communication with the passageway to facilitate the separation of the phases and the flow of the heavy phase into the second chamber; a valve seat defined by a wall of the barrier means disposed about the passageway; and a flexible flap valve means extending over the valve seat having one portion of the edge fixed to the barrier means and the other portions of the edge free, the flap means having a specific gravity greater than blood and normally sealing off the passageway to provide a barrier between first and second chambers, and when subjected to a predetermined centrifugal force, the flap means flexes away from the valve seat to open the passageway to provide communication between the chambers to permit the major portion of the light phase to travel to the first chamber and the heavy solid phase to travel to the second chamber, and upon cessation of the applied centrifugal force, the flap means returns to its normal position on the valve seat to seal off the passageway and provide a barrier between the first and second chambers (claim 1) that fulfills the specific embodiments of claims 77-79 and 83-86. Regarding claims 81 and 82, it is reasonable to conclude that the thickness of the flap would fall between 1-5 mm given the scale of the drawing provided.

7. Applicant argues that the centrifuge tube disclosed by Ayres does not anticipate the instant centrifuge tube because the flap described by Ayres does not divide the upper and lower chambers. This has been considered but not found persuasive. The flexible flap valve of Ayres

Art Unit: 1643

effectively seals off the passage between the first and second chambers (claim 1, lines 32-35) which anticipates the instant claims.

8. Claims 39-48, 56-76 and 80 remain objected to for being dependent on rejected claims.

9. All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/890,649

Page 5

Art Unit: 1643

Karen A. Canella, Ph.D.

8/22/2005

Karen A. Canella
KARENA CANELLA PH.D
PRIMARY EXAMINER